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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: Harbinger Medical, Inc.

Contact Person: Harold Holum
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Date Prepared: May 24, 2002

Trade Name: Micro-Induction 1000 system

Classification Name: and Number:	Electrocardiograph Class II, 21 CFR 870.2340	Electrode Electrocardiograph Class II, 21 CFR 870.2360
Product Code:	DPS	DRX

Predicate Device(s): The Micro-Induction 1000 system is substantially equivalent to the Cambridge Heart CH 2000 Cardiac Diagnostic System (K950018 – K983102 – K001034), and the Cambridge Heart Micro-V Alternans Sensor (K002230) and Cambridge Heart Hi-Res ECG Electrode (K962115) all manufactured by Cambridge Heart, Inc. Harbinger Medical also considers the MI 1000 to be substantially equivalent to the Zymed Model 2010 Holter Scanner (K955015), manufactured by Zymed, Inc., and other similar devices made by other manufacturers.

Device Description: The device consists of an IBM compatible PC, nine skin surface ECG type electrodes, one electronics board, a patient interface module and software. Seven of the electrodes are used for sensing cardiac electrical activity. The remaining two electrodes are used to apply low level current pulses (maximum of 40 milliamps) to the patient. This technology uses noninvasive, externally applied, subthreshold (low amplitude) far-field stimulus while acquiring electrocardiogram data.

The MI-1000 system is a tool used to identify heart cells that are significantly less stable than normal or conduct slower than normal and, thus, are an indication of cardiac electrical problems.

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Intended Use:

The MI-1000 is used to measure Wavelet Surface Residuum indices at rest and during low level electrical stimulation during the cardiac refractory period. This data is presented in a graphical format for interpretation by a trained physician. The MI-1000 is also used for the measurement of SAECG indices. The MI-1000 should be used only as an adjunct to clinical history and the results of other noninvasive and/or invasive tests.

Functional and Safety Testing:

Functional and safety testing of the Micro-Induction 1000 system consisted of bench and human clinical testing. Examination of device function was done under conditions similar to those found in normal usage to ensure conformance to product specifications. The results of the examination and testing were successful; the device performed as designed and met or exceeded all product specifications. Human clinical study data was collected on over 264 patients at two sites in the United States and one site in Europe.

Conclusion:

The Micro-Induction 1000 system is substantially equivalent to the Cambridge Heart CH 2000 Cardiac Diagnostic System (K950018 – K983102 – K001034) and the Cambridge Heart Micro-V Alternans Sensor (K002230) and Cambridge Heart Hi-Res ECG Electrode (K962115) all manufactured by Cambridge Heart, Inc. Harbinger Medical also considers the MI 1000 system to be substantially equivalent to the Zymed Model 2010 Holter Scanner (K955015), manufactured by Zymed, Inc. and other similar devices made by other manufacturers. This conclusion is based upon the devices' similarities in functional design, materials, indications for use and low level of risk to the patient as demonstrated throughout the clinical studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2002

Mr. Harold Hoium
Harbinger Medical, Inc.
12086 Oxbow Drive
Eden Prairie, MN 55347

Re: K013615
Trade Name: Micro-Induction (MI) 1000 System
Regulation Name: Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulatory Class: Class II (two)
Product Code: DPS
Dated: February 27, 2002
Received: March 1, 2002

Dear Mr. Hoium:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for use Page

Device Name: Micro-Induction 1000 system

Indications for Use:

The MI-1000 is used to measure Wavelet Surface Residuum indices at rest and during low level electrical stimulation during the cardiac refractory period. This data is presented in a graphical format for interpretation by a trained physician. The MI-1000 is also used for the measurement of SAECG indices. The MI-1000 should be used only as an adjunct to clinical history and the results of other noninvasive and/or invasive tests.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013615